UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,664	08/29/2001	Tetsuo Nishikawa	HIRA.0016	4772

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/940,664	NISHIKAWA ET AL.
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>08 October 2003</u>.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-15</u> is/are pending in the application.

    4a) Of the above claim(s) <u>9,10,14 and 15</u> is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-8 and 11-13</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on <u>29 August 2001</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☒ All b)☐ Some * c)☐ None of:
       1.☒ Certified copies of the priority documents have been received.
       2.☐ Certified copies of the priority documents have been received in Application No. _____.
       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
    a) ☐ The translation of the foreign language provisional application has been received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

U.S. Patent and Trademark Office

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 and 11-13 in Paper No. 10/08/03 is acknowledged.

Claims 9-10 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10/08/03.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The IDS statements filed 8/29/01, 8/23/02, 9/11/02 and 12/06/02 have each been entered and considered. Initialed copies of the forms are included with this action.

Drawings

The drawings submitted with the application are suitable to the examiner.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 depends from claim 1 wherein the translation means can obtain 3 reading frames from an input cDNA sequence. Claim 2 sets forth that the translation means can obtain 3 or 6 frames. This lacks antecedent basis in claim 1- if the translation means only provides 3 frames, it will not provide 6, as set forth in claim 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sonnhammer et al. (1994).

Claim 1 is drawn to an amino acid frame indication system, which comprises input means, translation means for obtaining 3 frames, alignment means for aligning the input with sequences from a database, and display means which display the alignment on the 3 frames. Dependent claim 2 indicates that an amino acid sequence for the cDNA is determined by analysis of the alignment across the frames. Claims 5-8 set forth that the display means can display the alignments as segments, in colors, in text, and show deletions and insertions. A method of using the system is also claimed (claim 13).

Sonnhammer et al. (Sonnhammer et al. 1994 CABIOS Vol. 10 No. 3 pages 301-307) disclose a system (pages 301-305) that identifies amino acid coding sequences. The system comprises input means for inputting the DNA sequence (which can be cDNA); translation means which generate open reading frame predictions in 3 frames, and alignment means for aligning the predicted sequences against sequences in a database. The alignments can then be displayed wherein the 3 frames are shown, along with the original sequence, and the matches are shown (with insertions or deletions) as segments with text, in colors across the frames (See figure 4). A

method of using the system is also disclosed.   As such, this meets the limitations of the rejected claims.

Claims 1-6, 8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearson (1997).

Claim 1 is drawn to an amino acid frame indication system, which comprises input means, translation means for obtaining 3 frames, alignment means for aligning the input with sequences from a database, and display means which display the alignment on the 3 frames. Dependent claim 2 indicates that an amino acid sequence for the cDNA is determined by analysis of the alignment across the frames. Claims 3 and 4 indicate that codon gaps can specifically be taken into account in the alignment means. Claims 5-6 and 8 set forth that the display means can display the alignments as segments, in text, and show deletions and insertions. A method of using the system is also claimed (claim 13).

Pearson et al. (Pearson et al. 1997 Genomics Vol. 46 pages 24-36) disclose a system for identifying an amino acid sequence for a DNA sequence. This system comprises an input means for inputting the DNA sequence (which can be cDNA), translation means for translating the sequence in all three frames, and alignment means for generating alignments between the generated amino acid sequences and amino acid sequences in a database. The display means can display the alignment along the frames, in segments, with text. The display means can show insertions, deletions and gaps (see Figure 1). The FASTY system can determine the true codon and assign a more likely amino acid sequence (see figure 2). The systems of Pearson use Smith-Waterman algorithms which specifically allow for the inclusions of gaps in alignments. A method of using the system is also disclosed. Therefore, this disclosure meets the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearson (1997) as applied to claims 1-6, 8 and 13 above, in view of Koleszar et al. (US 6,519,583 B1).

Claims 11 and 12 set forth that the system comprises an editing means, for editing the cDNA sequence and a resetting means. The editing can be done while displaying the text of the alignment.

As set forth above, Pearson et al. (Pearson et al. 1997 Genomics Vol. 46 pages 24-36) disclose a system for identifying an amino acid sequence for a DNA sequence. This system comprises an input means for inputting the DNA sequence (which can be cDNA), translation means for translating the sequence in all three frames, and alignment means for generating alignments between the generated amino acid sequences and amino acid sequences in a database. The display means can display the alignment along the frames, in segments, with text. The display means can show insertions, deletions and gaps (see Figure 1). The FASTY system can determine the true codon and assign a more likely amino acid sequence (see figure 2). The systems of Pearson use Smith-Waterman algorithms which specifically allow for the inclusions of gaps in alignments. At page 25, Pearson indicates that deliberate changes/ edits were made in the test cDNAs to analyze the effectiveness of the system prior to performing the translation and alignment tests. However, no specific editing means or resetting means are specifically disclosed, nor does Pearson disclose the editing of sequence information while the alignment is displayed.

Koleszar et al. (US 6,519,583 B1) disclose graphical viewers for biomolecular sequence data. These viewers allow for the display of input sequences, and their alignments to other known sequences from various databases. The viewer comprises editing means, reset means, and it appears these functions are available when alignments are displayed. See figures 4, 6, 8 as well as the specification.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have added an editing means to the system set forth by Pearson. One of skill in the art would have been motivated to have added the editing means of Koleszar to have enabled the user to correct errors and frameshifts detected by the methods of Pearson. The

correction of these types of errors would have been critical for the further study, and annotation of sequences in databases to ensure the most correct information was available. One of skill in the art would have had a reasonable expectation of success in adding such an editing feature to the system of Pearson, as the systems of both Pearson and Koleszar act on similar data, and have a similar underlying structure. Therefore the invention as a whole would have been prima facie obvious at the time of the invention absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. In January, after the move to the new facilities, the phone number will be: (571) 272-0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. In January, after the move to the new facilities, the phone number will be: (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
12/19/03

MARY K. ZEMAN
PRIMARY EXAMINER